



DEPARTMENT OF HEALTH AND HUMAN SERVICE

Southwest Region

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Food and Drug Administration  
Denver District Office  
Bldg. 20-Denver Federal Center  
P.O. Box 25087  
6<sup>th</sup> Avenue & Kipling Street  
Denver, Colorado 80225-0087  
Telephone: 303-236-3000  
FAX: 303-236-3100

October 12, 2000

**WARNING LETTER**  
**REISSUE**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Mr. Myong Kon Ko, Owner  
MS Foods, Inc.  
157 S. Buchanan Avenue  
Louisville, Colorado 80027

Ref. #: DEN-00-40

Dear Mr. Ko:

Investigator Eric S. Myskowski of this office inspected your bean sprout production facility located at 10625 Reed St., Broomfield, CO on July 28, 2000. The inspection found that you have failed to adopt effective preventative controls to reduce the risk of raw sprouts serving as a vehicle for foodborne illness and to assure that sprouts are not adulterated under the food safety provisions of the Federal Food, Drug, and Cosmetic Act (the Act). The inspection also revealed your operations are in serious violation of the Federal Regulations for Good Manufacturing Practices (GMP's) which are established in Title 21, Code of Federal Regulations, Part 110 (21 CFR 110).

Specifically, your sprouts are adulterated within the meaning of section 402(a)(4) of the Act because they are being produced under insanitary conditions that may render the sprouts injurious to health. The conditions under which the sprouts are being produced are considered insanitary since effective preventive controls, particularly microbial testing of spent irrigation water, have not been adopted and implemented by your sprouting facility, and an effective alternative is not in place.

Your sprouts are also adulterated with the meaning of 402(a)(4) of the Act because they have been prepared, packed or held under insanitary conditions whereby they may have been contaminated with filth or whereby they may have been rendered injurious to health. For example:

You have failed to store raw materials under conditions that will protect against contamination as required under 21 CFR 110.80(a). Specifically, raw material mung beans were being stored MS

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outside your facility where they were exposed to weather elements, pests, insects and other potential sources of contamination.

Failure to maintain your facility in a sanitary condition sufficient to prevent food from becoming adulterated as required under 21 CFR 110.20 and 110.35. Specifically:

Flies were observed throughout the processing and storage areas in direct contact with finished and in-process sprout products.

A cat was observed wandering throughout the processing and storage area.

Openings were observed in walls, ceilings and floors providing entryways for vermin, pests and insects.

Condensation from a refrigeration motor was observed dripping directly onto finished product containers.

We may take further action if you do not promptly correct these violations. For example, we may take further action to seize your products and/or enjoin your firm from operating.

It is necessary for you to take action on this matter now. Please let this office know, in writing, within fifteen (15) working days from the date you receive this letter as to the steps you are taking to correct these problems. We also ask that you explain how you plan to prevent these violations from happening again. If you need more time, please explain the reason for your delay, and when you expect the corrections to be completed.

This letter does not list all the violations at your facility. It is your responsibility to make sure you follow all the requirements of the Act and associated regulations. For your information, I have included with this letter, copies of the following industry guidance documents: "Reducing Microbial Food Safety Hazards for Sprouted Seeds," and "Sampling and Microbial Testing of Spent Irrigation Water During Sprout Production." These documents, which were also provided to you during the inspection, are intended to assist the sprout industry in producing safe products.

Your reply should be sent to the attention of H. Tom Warwick, Compliance Officer, at the above address. You may contact Mr. Warwick at (303) 236-3054 if you have any questions regarding this letter.

Sincerely yours,



Thomas A. Allison  
District Director

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Enclosures: As Stated